EXHIBIT 11

United States General Accounting Office

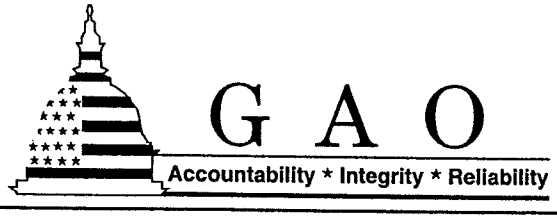
GAO

Report to Congressional Committees

September 2001

MEDICARE

Payments for Covered Outpatient Drugs Exceed Providers' Cost



GAO-01-1118

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14 percent and 77 percent below AWP. Medicare makes no separate payments for costs associated with supplying or administering oral drugs.

Private and other public payers use differing payment methods for drugs and their administration. Private health plans use their drug-purchase and patient volume to negotiate favorable prices for drugs and the physician and supplier services related to supplying or delivering the drugs. Other public payers also use their purchasing volume along with information about actual transaction prices from private payers to lower their drug payments. VA and certain other government agencies use the Federal Supply Schedule (FSS) prices for drugs. [10] State Medicaid programs reimburse for drugs using formulas based on standard price lists but subsequently receive rebates from the manufacturers calculated using the average manufacturer price (AMP), to substantially lower their net prices for drugs.[11] Both the FSS and the AMP are derived from actual market transaction data reported by drug manufacturers. In limited instances, VA also uses competitive bidding approaches to obtain lower drug prices, an approach that Medicare has used in limited demonstration projects.

We recommend that the Administrator of CMS take steps to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. We recommend that the CMS Administrator evaluate expanding competitive bidding approaches to setting payment levels. We also recommend that the CMS Administrator closely monitor beneficiary access to covered drugs in light of any changes to reimbursement.

[10]FSS prices are available to any federal agency that directly procures pharmaceuticals, including VA medical centers, the Department of Defense (DOD), the Bureau of Prisons, the Public Health Service (PHS), and other designated entities such as the District of Columbia, U.S. territorial governments, the Indian Health Service, and some state veterans homes. Manufacturers must also sell brand-name drugs listed on the FSS to four federal drug purchasers—VA, DOD, PHS, and the Coast Guard—at a price at least 24 percent lower than the nonfederal average manufacturer price, a ceiling price that is lower than the FSS price for many drugs.

[11]State Medicaid programs generally pay pharmacies a dispensing fee for each prescription and physicians a fee for administering the drugs.

Background

Although Medicare reimburses providers for roughly 450 unique drugs under part B, a small number of products accounted for the majority of Medicare spending and volume.[12] In 1999, the 20 highest expenditure drugs accounted for 75 percent of total Medicare drug spending and the 20 highest volume drugs accounted for 93 percent of total units.[13] (See tables 1 and 2.) Combined, these two groups of drugs yielded 35 unique drugs, accounting for 82 percent of total drug spending and 95 percent of total drug units.[14]

[12]Each covered drug is identified by an alphanumeric code under the HCFA Common Procedure Coding System (HCPCS), which specifies the drug name, method of administration, and dosage.

[13]Our analysis of drug acquisition costs excluded four high-volume and high-expenditure drugs. Specifically, we excluded a code for "not otherwise classified antineoplastic drugs," two antihemophilia clotting factors, and a radiopharmaceutical. We could not collect acquisition cost data on "not otherwise classified antineoplastic drugs" because it does not refer to a specific product. The clotting factors, which are typically billed by non-physician suppliers, were not included for two reasons. First, we were unable to obtain adequate pricing information for these products, a problem also encountered by HHS OIG in its prior work on drug reimbursement. Second, these products differ significantly from other pharmaceutical products discussed in this report. Their source material is collected from human donors; their manufacturing, storage, and distribution processes differ from other products; and they are administered to a very small patient population. The excluded radiopharmaceutical, Technetium TC Sestamibi, is used by cardiologists in certain diagnostic imaging procedures. Since Medicare only began requiring data on AWPs to reimburse for radiopharmaceutical products in 2001, these data are currently being developed.

[14]Units are defined as the number of claims for each drug times the number of units specified by its HCPCS label.

Table 1: Medicare Part B Drugs by Share of Total Medicare Drug Spending, 1999

Drug name	Share of total Medicare drug spending (percentage)
Leuprolide acetate (for depot suspension)	15.1
Epoetin alpha for non-ESRD use	9.5
Goserelin acetate implant	7.9
Ipratropium bromide, unit dose form	6.4
Albuterol, unit dose form	6.3
Paclitaxel	6.2
Carboplatin	2.9
Pamidronate disodium	2.8
Irinotecan	2.0
Gemcitabine HCl	1.9
Rituximab	1.8
Filgrastim (G-CSF) 480 mcg	1.7
Leucovorin calcium	1.6
Docetaxel	1.5
Factor VIII (antihemophilic factor, recombinant)	1.3
Technetium TC Sestamibi	1.2
Hylan G-F 20	1.2
Filgrastim (G-CSF) 300 mcg	1.2
Not otherwise classified antineoplastic drugs	1.2
Dolasetron mesylate, injection	1.2
Subtotal, 20 highest-expenditure drugs and biologicals	74.9
All other Medicare-covered drugs and biologicals	25.1
Total	**100.0**

Source: GAO analysis of data from the Medicare Part B Extract and Summary System (BESS).

Table 2: Medicare Part B Drugs by Share of Total Medicare Units, 1999

Drug name	Share of total units (percentage)
Albuterol, unit dose form	65.8
Ipratropium bromide, unit dose form	8.2
Epoetin alpha for non-ESRD use	3.4
Dolasetron mesylate, injection	3.3
Albuterol, concentrated form	2.6
Mycophenolate mofetil, oral	1.7
Cromolyn sodium, unit dose form	1.2
Heparin sodium	1.0
Cyclosporine, oral	0.9
Ondansetron HCl, injection	0.8
Tacrolimus, oral	0.7
Prednisone, oral	0.6
Acetylcysteine, unit dose form	0.5
Botulinum toxin, type A	0.5
Imiglucerase	0.4
Factor VIII (antihemophilic factor, human)	0.4
Dexamethasone sodium phosphate	0.4
Leucovorin calcium	0.3
Saline solution, sterile	0.3
Granisetron HCl, injection	0.3
Subtotal, 20 highest-volume drugs and biologicals	93.3
All other Medicare-covered drugs and biologicals	6.7
Total	**100.0**

Note: Units are defined as the number of Medicare-allowed services. Each drug has a standard unit dosage specified by the HCPCS code.

Source: GAO analysis of data from BESS.

The drugs provided by physicians account for the largest share of Medicare expenditures for drugs under part B, while billing volume is dominated by the drugs provided by pharmacy suppliers. Drugs provided in the physician office setting accounted for over 75 percent of Medicare spending for drugs in 1999. (See table 3.) Three specialties, hematology/oncology, medical oncology, and urology, bill Medicare primarily for drugs used in the treatment of cancer and represented 80 percent of total Medicare payments to physicians for drugs. By contrast, pharmacy suppliers accounted for over 80 percent of Medicare drug billing volume and less than 20 percent of corresponding payments. Two inhalation therapy drugs dominated these home-administered products, accounting for 88 percent of Medicare volume in the home setting. When the drug is delivered in a physician's office, Medicare makes a separate

additional payment through the physician fee schedule for the physician or his or her staff administering a drug. When the drug is administered via DME in the home, Medicare pays separately for DME, the drug, and associated supplies as well as a monthly dispensing fee for providing nebulizer drugs.

Table 3: Medicare Part B Drug Spending and Volume by Place of Service, 1999

Place of service	Total spending	Share of total spending (percentage)	Total units	Share of total units (percentage)
Physician office	$3,021,662,605	76.2	142,247,564	14.9
Home	727,559,447	18.3	759,461,862	79.7
Other[a]	218,297,305	5.5	51,770,956	5.4
Total	**$3,967,519,357**	**100.0**	**953,480,382**	**100.0**

[a]"Other" includes, for example, immunization centers, end-stage renal disease treatment facilities, and independent laboratories.

Note: Medicare's payment is 80 percent of the allowed amount and the beneficiaries' share is 20 percent, after they have fulfilled their annual deductible requirements. Units are defined as the number of Medicare-allowed services, as specified by the HCPCS code.

Source: GAO analysis of data from BESS.

Medicare Payments for Drugs Are Based on Published AWPs

Medicare bases its reimbursement to physicians and other providers of drugs on AWP, which is often described as a "list price," "sticker price," or "suggested retail price," reflecting the fact that AWP is not necessarily the price paid by a purchaser or a consistently low or "wholesale" price. AWPs are published for each drug identified by a National Drug Code (NDC).[15] Manufacturers periodically report AWPs for NDCs to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, or First Data Bank, which compiles the National Drug Data File. Publishers of AWPs and other drug prices stated that they list the prices as reported to them by the manufacturers. There is no required frequency for manufacturers to report AWPs, but publishers said they attempt to update AWPs at least annually. Medicare carriers, the contractors responsible for paying part B claims, use published AWPs to

[15]NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first part of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug. Each NDC is specific to a chemical entity, dosage form, manufacturer, strength, and package size. For example, a drug made by one manufacturer, in one form and strength, but in three package sizes, would have three NDCs.

determine the Medicare-allowed amount, or payment level, which is 95 percent of AWP for each HCPCS-coded drug. Because one HCPCS code may have multiple NDCs that match the HCPCS-coded product's definition, the carriers may determine the Medicare payment by analyzing multiple NDCs. [16]

Drug Supply Chain Involves Multiple Parties and Arrangements That Influence the Net Cost to the End Purchaser

Pharmaceutical sales and distribution networks can involve multiple entities and purchasing arrangements that affect the actual acquisition price of the drug for the end purchaser that supplies it to a Medicare beneficiary. Physicians and pharmacies can purchase the kinds of drugs covered under Medicare part B from general or specialty pharmaceutical wholesalers or they can have direct purchase agreements with manufacturers. Purchasers may belong to GPOs that pool the purchasing of multiple entities and negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for a drug for different end users, such as physicians, pharmacies, or hospitals.

Determining physicians' or other providers' actual acquisition cost of drugs is complicated by certain practices in the pharmaceutical marketplace that may result in transaction prices paid at the time of sale that do not reflect the final net cost to the purchaser. For example, manufacturers or wholesalers may offer purchasers rebates based on the volume of products purchased. In addition, manufacturers may establish "chargeback" arrangements for end purchasers, under which the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler sells the product to the purchaser for the lower price negotiated with the manufacturer, and then asks the manufacturer to pay back the difference between the wholesaler's price and the negotiated price.

[16]For single-source drugs (drugs whose manufacturer is the sole source for a given product), Medicare's payment is 95 percent of the drug's AWP. For multisource drugs (drugs with generic equivalents or drugs for which there are two or more competing brand-name products), the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand-name product AWP. Within these guidelines, each carrier contracting with Medicare to process claims has discretion to determine which NDCs should be used to calculate the payment rate for each HCPCS code. This can lead to variation in payment amounts among carriers for the same HCPCS-coded drug. By October 1, 2002, all payers, including Medicare, will be required to process and pay drug claims by NDC, rather than HCPCS code, in compliance with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191). 65 Fed. Reg. 50312, 50370 (to be codified at 42 C.F.R. 162.1002(c)).

EXHIBIT 12

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Reimbursement of Albuterol

JUNE GIBBS BROWN
Inspector General

JUNE 2000
OEI-03-00-00311

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

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OEI's Philadelphia Regional Office prepared this report under the direction of Robert A. Vito, Regional Inspector General, and Linda M. Ragone, Deputy Regional Inspector General. Principal OEI staff included:

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EXECUTIVE SUMMARY

PURPOSE

This report compares the amount Medicare reimburses for albuterol with (1) the amounts reimbursed by Medicaid and the Department of Veterans Affairs, and (2) prices available at pharmacies.

BACKGROUND

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs which are necessary for the effective use of durable medical equipment (DME). One such drug, albuterol, is commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Medicare allowed approximately $246 million for albuterol in 1999.

The Health Care Financing Administration (HCFA) contracts with four DME regional carriers who determine reimbursement amounts for nebulizer drugs. In general, the Medicare reimbursement amount for a covered drug is 95 percent of the drug's average wholesale price (AWP). Of this amount, Medicare pays 80 percent while the beneficiary is responsible for a 20 percent copayment. Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, Blanket Purchase Agreements, and VA national contracts.

We obtained reimbursement amounts for albuterol from Medicare, Medicaid, and the VA. We also determined retail prices for albuterol by contacting chain and Internet pharmacies. We compared Medicare's current reimbursement amount for albuterol to amounts reimbursed by Medicaid and the VA, and prices available at pharmacies.

FINDINGS

Medicare and its beneficiaries would save $120 million or $209 million a year if albuterol was reimbursed at amounts available through other Federal sources

The Medicare reimbursement amount for albuterol is almost seven times greater than the VA price. The VA purchases generic albuterol through the Federal Supply Schedule for only $0.07 per milligram (mg), while Medicare reimburses at $0.47 per mg. We estimate

that Medicare and its beneficiaries would save $209 million a year if reimbursement for albuterol was set at the amount available to the VA under the Federal Supply Schedule. Medicare's reimbursement amount for albuterol is almost double Medicaid's upper limit of $0.24 per mg. We estimate that Medicare and its beneficiaries would save $120 million if Medicare's reimbursement amount for albuterol equaled Medicaid's upper limit amount.

Medicare and its beneficiaries would save $47 million or $115 million a year if Medicare reimbursed albuterol at prices available at chain and Internet pharmacies

Customers walking into nearly all of the chain pharmacies we contacted would pay less than the Medicare reimbursement amount for albuterol. Prices at these pharmacies ranged from a low of $0.24 cents per mg to a high of $0.48 per mg for a single box supply. If Medicare reimbursement was set at the pharmacies' median price of $0.38 per mg, Medicare and its beneficiaries could save $47 million a year on albuterol. Some pharmacies offered even lower prices for larger quantity purchases. Prices for albuterol at the Internet pharmacies we visited ranged from $0.21 to $0.31 per mg for a single box supply. Medicare would save almost $115 million a year if its reimbursement amount for albuterol equaled the median Internet pharmacy price of $0.25 per mg. As with the chain pharmacies, discounts for larger quantity purchases were sometimes available.

RECOMMENDATION

The information in this report adds to the evidence which shows that Medicare pays too much for albuterol. The finding that Medicare pays more than the VA for albuterol is not surprising since the VA acts as a purchaser of drugs while Medicare reimburses suppliers after-the-fact. Even allowing for this difference in payment methods, Medicare's reimbursement amount for albuterol – almost seven times higher than the cost of the drug to the VA – seems excessive. It also seems excessive that Medicare beneficiaries pay more in just monthly copayments for albuterol than the VA pays for a whole month's supply of the drug. Medicaid, which reimburses for drugs in a manner similar to Medicare, has a federally-mandated upper limit for albuterol. The upper limit amount established by HCFA is about half of the Medicare amount. In addition, anyone with a prescription can walk into a retail chain pharmacy or visit an Internet pharmacy and pay a price for albuterol which is usually below the Medicare reimbursement amount. These findings raise serious doubts about the accuracy and efficacy of Medicare's payment policy.

This report found that Medicare would save between $47 million and $209 million by lowering its reimbursement amount for albuterol to prices available through other sources. It is important to note that 20 percent of these savings would directly benefit Medicare beneficiaries through reduced copayments.

We continue to support the need for lower albuterol prices for the Medicare program and its beneficiaries. We realize, however, that HCFA's power to lower drug prices through the use of its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. In past reports, we recommended a number of other options for lowering albuterol payments. These recommendations included (1) greater discounting of AWPs, (2) basing payments on supplier acquisition costs, (3) establishing manufacturers' rebates, and (4) using competitive bidding. We continue to strongly believe that action needs to be taken to lower unreasonable drug reimbursement amounts.

Agency Comments

The HCFA concurred with our recommendation, noting that basing reimbursement on acquisition cost is probably the best way to ensure that Medicare pays fair prices for covered drugs. Additionally, HCFA gave a detailed account of their numerous attempts to lower unreasonable drug reimbursement amounts in the Medicare program. Currently, HCFA plans to utilize a number of more accurate drug prices developed by First Databank, publisher of a pricing compendium used by the pharmaceutical industry. HCFA requested that Medicare contractors use these prices when calculating their drug reimbursement amounts. The HCFA also commented that they are working to develop a comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix E.

We commend HCFA's efforts to lower Medicare drug reimbursement rates. We fully support attempts to obtain more accurate prices for the Medicare program. We believe that HCFA's request that Medicare contractors use the more accurate prices supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner.

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Medicaid Reimbursement Amounts

We obtained from HCFA the Medicaid upper limit amount for albuterol as of April 1, 2000. We also accessed the Medicaid Drug Rebate Initiative system to determine the Medicaid rebate amounts for albuterol. We used the most recent rebate amounts available for each NDC code, which in most cases was the fourth quarter of 1999. Four of the 17 NDCs reviewed did not have any rebate information available. We calculated the median milliliter (ml) rebate amount for the remaining 13 NDCs in order to determine a single Medicaid rebate amount.

VA Pricing

To determine the VA's fourth quarter 1999 costs for albuterol, we obtained a file from the VA containing their contracted prices. The VA pricing file contained Federal Supply Schedule prices for 7 of the 17 matching albuterol NDCs. To determine a single VA price, we calculated the median price per ml for these seven NDCs.

Pharmacy Pricing

We contacted three chain pharmacies in each of eight cities (Atlanta, Boston, Chicago, Dallas, Kansas City, New York, Philadelphia, and San Francisco). We also visited the websites of three Internet pharmacies. Our review of the applicable NDCs indicates that the smallest amount of unit dose albuterol available for purchase is 75 ml, which is usually supplied in one box of twenty-five 3 ml vials. Therefore, we requested that the pharmacies provide their price for this amount of the drug. To determine if there were volume discounts available, we asked for the price of four boxes of albuterol (300 ml), which is a typical monthly usage amount for the drug. We then calculated the median price per ml of a single box supply for both chain and Internet pharmacies.

Conversion of Prices

The HCPCS code for the unit dose form of albuterol, J7619, is reimbursed per milligram (mg). Medicaid's upper limit is based on 1 ml of 0.083 percent albuterol solution. The NDCs used to determine the Medicaid rebates, VA prices, and pharmacy prices were all based on 3 ml vials of 0.083 percent albuterol solution. Consequently, we needed to convert milliliter prices of albuterol into milligram prices.

A 3 ml vial of 0.083 percent albuterol solution contains 2.5 mg of albuterol. Therefore, 1 ml of solution contains 0.833 mg of albuterol (2.5 divided by 3). After determining a per ml price for albuterol from each of the sources, we converted this to a per mg price simply by dividing the per ml price by 0.833. For example, by dividing the Medicaid upper limit price of $0.20 per ml by 0.833, we calculated that the Medicaid upper limit price equals $0.24 per milligram.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for albuterol to amounts available at the VA, Medicaid, chain pharmacies, and Internet pharmacies. We determined the percentage difference in prices by subtracting the source price from the Medicare price, and then dividing this number by the Medicare price. These percentages indicate how much Medicare would save if reimbursement for albuterol was based on prices provided by other sources. We then multiplied these percentages by Medicare's 1999 allowed charges for albuterol in order to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

FINDINGS

Medicare and its beneficiaries would save $120 million or $209 million a year if albuterol was reimbursed at amounts available through other Federal sources

The Medicare reimbursement amount for albuterol is almost seven times greater than the VA price

The median Federal Supply Schedule price available to the VA for generic albuterol is only $0.07 per mg, compared to $0.47 per mg for Medicare. We estimate that Medicare and its beneficiaries would save $209 million a year if reimbursement for albuterol was set at the amount available to the VA under the Federal Supply Schedule. This savings represents 85 percent of the $246 million in Medicare allowed charges for albuterol in 1999. A Medicare beneficiary using 250 mg of albuterol per month would pay more in just the Medicare copayment ($23.50) than the VA would pay ($17.50) to purchase the drug outright. Table 1 below compares the Medicare reimbursement amount to prices available through other sources. It also provides potential Medicare savings and beneficiary copayments based on various reimbursement levels.

TABLE 1: COMPARISON OF ALBUTEROL PRICES

Pricing Source	Price per mg	Cost of Typical Individual Monthly Usage (250 mg)	Monthly Beneficiary Copayment Based on Source Price	Potential Annual Medicare and Beneficiary Savings
Medicare Reimbursement Amount	$0.47	$117.50	$23.50	N/A
Department of Veterans Affairs Median Cost	$0.07	$17.50	$3.50	$209,478,193
Medicaid Upper Limit Amount	$0.24	$60.00	$12.00	$120,449,961
Chain Pharmacy Median Price	$0.38	$95.00	$19.00	$47,132,593
Internet Pharmacy Median Price	$0.25	$62.50	$12.50	$115,213,006

The Medicare reimbursement amount for albuterol is nearly twice the Medicaid reimbursement amount

The HCFA has set Medicaid's upper limit for albuterol at $0.24 per mg, yet Medicare DMERCs reimburse albuterol at $0.47 per mg. We estimate that Medicare and its

beneficiaries would save $120 million a year if Medicare's reimbursement amount for albuterol equaled Medicaid's upper limit amount. These potential savings represent almost one-half of Medicare allowed charges for albuterol in 1999.

In addition to the lower reimbursement amount, Medicaid also receives a rebate for generic albuterol of approximately $0.01 per mg. This would create an additional $5.2 million in savings a year for Medicare.

Medicare and its beneficiaries would save $47 million or $115 million a year if Medicare reimbursed albuterol at prices available at chain and Internet pharmacies

Customers walking into nearly all of the chain pharmacies we contacted would pay less than the Medicare reimbursement amount for albuterol

Twenty-two of the 24 pharmacies we contacted charge customers less than the Medicare reimbursement amount for albuterol. Prices at the 24 chain pharmacies ranged from a low of $0.25 cents per mg to a high of $0.48 per mg for a single box supply. Based on the 24 pharmacies' median price of $0.38 per mg, Medicare and its beneficiaries would save $47 million a year on albuterol.

Some pharmacies offered even lower prices for larger quantities of the drug. For example, one chain pharmacy offered four boxes of albuterol (a typical monthly supply) for $35.94, a cost of only $0.14 per mg. Medicare would have reimbursed $117.50 for the same amount. If Medicare reimbursed albuterol at $0.14 per mg, it would save 70 percent of current albuterol payments. The prices for albuterol available at the chain pharmacies we contacted are presented in Appendix C.

Customers purchasing albuterol at Internet pharmacies would pay lower prices than Medicare

Prices for albuterol at the Internet pharmacies we visited ranged from $0.21 to $0.31 per mg for a single box supply. Medicare would save almost $115 million a year if its reimbursement amount for albuterol equaled the median Internet pharmacy price of $0.25 per mg. As with the chain pharmacies, discounts for larger quantity purchases were sometimes available. The lowest price found for a four-box supply of albuterol was $41.94, a cost of $0.17 per mg. If Medicare reimbursed albuterol at $0.17 per mg, it would save 64 percent of current albuterol payments. The prices for albuterol at each of the Internet pharmacies we contacted are presented in Appendix D.

RECOMMENDATION

The information in this report adds to the evidence which shows that Medicare pays too much for albuterol. The finding that Medicare pays more than the VA for albuterol is not surprising since the VA acts as a purchaser of drugs while Medicare reimburses suppliers after-the-fact. Even allowing for this difference in payment methods, Medicare's reimbursement amount for albuterol – almost seven times higher than the cost of the drug to the VA – seems excessive. It also seems excessive that Medicare beneficiaries pay more in just monthly copayments for albuterol than the VA pays for a whole month's supply of the drug. Medicaid, which reimburses for drugs in a manner similar to Medicare, has a federally-mandated upper limit for albuterol. The upper limit amount established by HCFA is about half of the Medicare amount. In addition, anyone with a prescription can walk into a retail chain pharmacy or visit an Internet pharmacy and pay a price for albuterol which is usually below the Medicare reimbursement amount. These findings raise serious doubts about the accuracy and efficacy of Medicare's payment policy.

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comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix E.

OIG Response

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APPENDIX A

Previous OIG Reports on Albuterol Reimbursement

Are Medicare Allowances for Albuterol Sulfate Reasonable? **(OEI-03-97-00292), August 1998.** We found that Medicare would allow between 56 to 550 percent more than the VA would pay for generic versions of albuterol sulfate in 1998, and 20 percent more than the average Medicaid payment for albuterol sulfate in 1997. We also found that Medicare allowed 333 percent more than available acquisition costs for the drug in 1998. Customers of mail-order pharmacies would pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

A Comparison of Albuterol Sulfate Prices **(OEI-03-94-00392), June 1996.** We found that many of the pharmacies surveyed charged customers less than the Medicare allowed amount for generic albuterol sulfate. The five buying groups surveyed had negotiated prices between 56 and 70 percent lower than Medicare's reimbursement amount for the drug.

Suppliers' Acquisition Costs for Albuterol Sulfate **(OEI-03-94-00393), June 1996.** We found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs for the drug. The Medicare program could have saved $94 million of the $182 million allowed for albuterol during the 14-month review period if Medicare reimbursement amounts had been based on average supplier invoice costs.

Medicare Payments for Nebulizer Drugs **(OEI-03-94-00390), February 1996.** We found that Medicare and its beneficiaries paid about $37 million more for three nebulizer drugs in 17 States than Medicaid would have paid for equivalent drugs. In addition, we found that the potential savings were not limited to the three nebulizer drugs and 17 states which were reviewed.

EXHIBIT 13

FILED UNDER SEAL

EXHIBIT 14

FILED UNDER SEAL

EXHIBIT 15

FILED UNDER SEAL

EXHIBIT 16

FILED UNDER SEAL

EXHIBIT 17

FILED UNDER SEAL

EXHIBIT 18

FILED UNDER SEAL

EXHIBIT 19

FILED UNDER SEAL